A COMPARATIVE STUDY OF LYMPHATIC MANIPULATION VERSUS INTERMITTENT PNEUMATIC COMPRESSION PUMP TO REDUCE LYMPHEDEMA AND ITS RELATED FUNCTIONAL LIMITATION IN POST RADICAL MASTECTOMY

A dissertation submitted in partial fulfillment of the requirement for the degree of

MASTER OF PHYSIOTHERAPY

(ELECTIVE –PHYSIOTHERAPY IN ORTHOPAEDICS)

To

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CERTIFICATE

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INTERNAL EXAMINER:

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THE DEGREE OF "MASTER OF PHYSIOTHERAPY"

AT

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CHENNAI

APRIL 2013

DECLARATION

I hereby declare and present my thesis work entitled **"A COMPARATIVE STUDY OF LYMPHATIC MANIPULATION VERSUS INTERMITTENT PNEUMATIC COMPRESSION PUMP TO REDUCE LYMPHEDEMA AND ITS RELATED FUNCTIONAL LIMITATION IN POST RADICAL MASTECTOMY".**

The outcome of original research work undertaken and carried out by me, under the guidance of **Prof. Mrs. L.Vinola M.P.T , R.V.S. College of Physiotherapy,** Sulur, Coimbatore.

I also declare that the material of this project work has not formed in anyway the basis for the award of any other degree previously from the Tamil Nadu Dr. M. G. R. Medical University, Chennai.

Place: SIGNATURE

Date:

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I. INTRODUCTION

Cancer known medically as a malignant neoplasm, is a broad group of various diseases, all involving unregulated cell growth. In cancer, cells divide and grow uncontrollably, forming malignant tumors, and invade nearby parts of the body. The cancer may also spread to more distant parts of the body through the lymphatic system or bloodstream. Not all tumors are cancerous. Benign tumors do not grow uncontrollably, do not invade neighboring tissues, and do not spread throughout the body. There are over 200 different known cancers that afflict humans. Most of all patients with terminal or advanced cancer suffer with poor mental health. Specifically, depression, anxiety, and adjustment disorders plague people with advanced or terminal cancer.

Women's health in recent years is more prone to cancer. It is being witnessed that urban population is developing breast cancer more than its rural counterpart. Lifestyle including food, mental health and hormonal imbalance has to be corrected to avoid such risks. Marriage at the right age and timely pregnancies also minimize risk of developing the disease.Cancer is curable if detected early and in terminal stages; it is the quality and not the quantity of life that really matters. Urban Indian women have fewer children and breastfeed them less than their rural counterparts, all of which increases their exposure to oestrogen.

Radical mastectomy is a surgical procedure in which the breast, underlying chest muscles including pectorals major, minor muscle and lymph nodes are removed as a treatment of breast cancer. It was developed by William Stewart Halted in 1882. Women being treated for breast cancer in US, Underwent radical mastectomy this is a

morbid surgery and is not performed in extreme cases. There are three categories of Mastectomy.

- Total Mastectomy
- Radical Mastectomy
- Partial Mastectomy

Total mastectomy is the procedure in which the entire breast tissue is removed, but axillary contents are undisturbed. Sometimes the "sentinel lymph node" that is, the first axillary lymph node that the metastasizing cancer cells would be expected to drain into is removed. This surgery is sometimes done bilaterally (on both breasts) on patients who wish to undergo mastectomy as a cancer-preventative measure. Patients who undergo simple mastectomy can usually leave the hospital after a brief stay. Frequently, a drainage tube is inserted during surgery in their chest and attached to a small suction device to remove subcutaneous fluid. These are usually removed several days after surgery as drainage decrease to less than 20-30 ml per day.

In modified radical mastectomy entire breast tissue is removed along with the axillary contents (fatty tissue and lymph nodes). In contrast to a radical mastectomy, the pectoral muscles are spared.

Radical mastectomy is the procedure involves removing the entire breast, the axillary lymph nodes, and the pectoralis major and minor muscles behind the breast. This procedure is more disfiguring than a modified radical mastectomy and provides no survival benefit for most tumors. This operation is now reserved for tumors involving the pectoralis major muscle or recurrent breast cancer involving the chest wall. Lymphedema is a major complication which arises due to post radical

mastectomy. Lymphedema develops after breast surgery because there is an alteration in the pathway that drains the fluid involved in the immune system. It can occur at any time after the surgery if untreated, it can become worse.

Lymphedema is an abnormal build up of fluid that causes swelling most often in the arms or leg. The condition develops when lymph vessels or lymph nodes are missing, impaired, damaged or removed. There are two types of lymphedema.

- Primary Lymphedema
- Secondary Lymphedema

Primary Lymphedema is rare and is caused by the absence of / or abnormalities in certain lymph vessels at birth.

Secondary Lymphedema occurs as a result of a blockage or interruption that alters the flow of lymph through the lymphatic system and can develop from an infection cancer, surgery, scar tissue formation trauma, DVT, radiation or other cancer treatment. The standard physiotherapy management for secondary lymphedema are lymphatic manipulation, intermittent pneumatic compression pump and decongestive therapy.

Lymphatic manipulation was developed by Danish Physical therapist Dr. Emil and Estrid Vodder, in the 1930. This technique developed as a result of their studies on the lymph vessel system. Lymphatic manipulation is a series of light rhythmic manipulation that stimulates Lymph flow. This rhythmical massage stimulates the lymphatic vessels.

The lymphatic vessels in our body play a key role in delivering nutrients and anti bodies, and other immune constituents to the tissue cells of the body and remove toxin, cell waste and their particles when the lymphatic vessel are not functioning properly due to blockages the body immunity drop and it is susceptible to the number of ailments such as infection, malignancy.

Lymphatic manipulation helps in removing these blockages and restores the lymphatic system to its normal stage. It also works on nervous system, lower blood pressure, reduces Stress and improves sleeping pattern. Lymphatic manipulation is both a preventive and a remedial treatment. It provides a major boost to the immune system. It has been proven to be very effective in the treatment of condition such as malignancy.

Intermittent pneumatic compression pump were at one time a standard treatment for lymphedema. These older types referred to as pneumatic compression device consist of an inflatable garment for the arm, leg or foot and an electrical pneumatic pump that fills the garment with compressed air, the garment is intermittently inflated and deflated with cycle times and pressures that vary between devices. Today there is a new generation pumps that act frequently with less pressure being applied.

1.2.NEED OF THE STUDY

There are many treatment to reduce lymphedema among subjects of post radical mastectomy, need of the study was to compare Lymphatic Manipulation is more effective or intermittent pneumatic compression pump is more effective to reduce lymphedema and its related functional limitations.

1.3. OBJECTIVE OF THE STUDY

- To evaluate the outcome of lymphatic manipulation as a component of physical therapy treatment for lymphedema compared to intermittent pneumatic compression pump.
- To determine whether the lymphatic manipulation or intermittent pneumatic compression pump removes Lymphedema and promotes recovery and improvement of functional activities among individual with secondary Lymphedema.

1.4.STATEMENT OF THE PROBLEM

The study was to compare Lymphatic Manipulation and Intermittent pneumatic compression pump to reduce lymphedema and its related functional limitation in post radical mastectomy.

1.4. HYPOTHESIS

1.4.1. Null Hypothesis

- There is no significant difference in lymphedema and its functional limitation following lymphatic manipulation and intermittent pneumatic compression pump post radical mastectomy subjects.

- There is no significant difference between lymphatic manipulation and intermittent pneumatic compression pump on reducing lymphedema and its related functional limitation among post radical mastectomy subjects.

1.4.2. Alternate Hypothesis

- There is significant difference in lymphedema and its functional limitation following lymphatic manipulation and intermittent pneumatic compression pump post radical mastectomy subjects.
- There is significant difference between lymphatic manipulation and intermittent pneumatic compression pump on reducing lymphedema and its related functional limitation among post radical mastectomy subjects.

1.5. OPERATIONAL DEFINITIONS

Lymphatic Manipulation

Lymphatic manipulation is a series of light rhythmic manipulation that stimulates Lymph flow. Manual lymph drainage is a gentle manual treatment technique based on four basic strokes.

Intermittent Pneumatic compression Pump

Intermittent pneumatic compression is a therapeutic technique used in medical devices that include an air pump and inflatable axillary sleeves, gloves or boots in a system designed to improve venous circulation in the limbs of patients who suffer edema.

Lymphedema

Lymphedema is an abnormal build up of fluid that causes swelling most often in the arms or leg. The condition develops when lymph vessels or lymph nodes are missing, impaired, damaged or removed.

Functional limitation

The limitation to perform a movement concerning daily living activities.

Radical Mastectomy

Radical mastectomy is a surgical procedure in which the breast, underlying chest muscles including pectorals major, minor muscle and lymph nodes are removed as a treatment of breast cancer.

II. REVIEW OF RELATED LITERATURE

SECTIONS

Section A : **Studies on the Effect of lymphatic manipulation among lymphedema subjects.**

Section B : **Studies on the Effect of pneumatic compression pump among lymphedema subjects.**

Section C : **Incidence of lymphedema among post radical mastectomy subjects.**

Section D : **Studies on reliability and validity of Tonometer.**

Section E : **Studies on reliability and validity of lymphedema Functioning, Disability and Health Questionnaire.**

Section A

Studies on the Effect of lymphatic manipulation among lymphedema subjects.

Henaeres.(1998) concluded, that an early physiotherapy group was treated by a physiotherapist with physiotherapy program including lymphatic manipulation. The controlled group received educational strategy alone, 116 women completed the one year follow up. Of these 18 developed secondary lymphedema, 14 in the control group and 4 in the intervention group. The difference was significant. Risk ratio 0:28, a survival analysis showed a significant difference. With secondary lymphedema being diagnosed four times earlier in the control group. These studies were made on lymphatic manipulation could be effective intervention in the prevention of secondary lymphedema in women for at least one year after surgery. For breast cancer involvingdissection of axillary lymph nodes.

Oxford Journals; annuals of oncology, Issue 4;PG 639-646, (2006.) the systematic review undertook a broad investigation of commonly investigated conservative therapies, including lymphatic manipulation, pneumatic pumps, limb elevation. All conservative therapies produced improvement in subjects arm. In symptoms quality of life where identified. Benefits in lymphatic manipulation improved functional limitation.

Khalil and Baker. (2007) concluded, the early physiotherapy could be an effective intervention in the prevention of secondary lymphedema in women for at least one year after surgery for breast cancer involving dissection of axillary lymph node.120 women who had breast surgery involving dissection of axillary lymph nodes were randomly assigned to a treatment group. Physiotherapist put the patient through a

program included lymphatic manipulation, Active and active assisted shoulder exercises. This group also received educational strategy. In controlled group educational strategy alone the incidence of clinical significant lymphedema reduction was noted.

Martin M.L et al.(2011) concluded, from a randomized controlled trial in 58 women post mastectomy lymphedema. The control group includes 29 patients with standard treatment pneumatic compression; the experimental group includes 29 patients with lymphatic manipulation. The therapy will be administrated daily for four weeks and the patient condition will be assessed. The primary outcome parameter, Is volume reduction of affected arm. The result of the study will provide information on the effectiveness of lymphatic manipulation and its impact on the quality of life and physical limitation of this patient.

Dr. Emil and Vodder (1936) concluded lymphatic manipulation is a form of manipulation that stimulates the lymphatic system with gentle strokes. The light strokes encourage the lymphatic system to eliminate metabolic waste product, excess fluid, and bacteria. The technique was invented by them.

David Goddard. (1998) concluded that the immune system protects the body against infection. It transports the nutrients to cells and eliminates metabolic wastes, toxins and excess fluids from the body. Lymphatic manipulation is also a very effective way of detoxing the body plus stimulating vital immune deficiency.

Section B

Studies on the Effect of pneumatic compression pump among lymphedema subjects.

Richmond and Donell, Archives of surgery (1985) concluded, prospectively the effect of a new compression device for lymphedema which utilizes, a short duration and high pressure cycle that provide a sequential milking pattern to the limb through multiple compartmental. Twenty five patients underwent 20 minute treatment at upper extremities showed a decrease in circumference measurement with the maximal reduction in occurring a wrist. Despite the high pressure no serum muscle enzymes level was noted this device reduce lymphedema in limbs.

Dini and Gozza,(Annuals of 1998) concluded, pneumatic compression is a frequently prescribed physical therapy for patient affected by post mastectomy lymphedema. But despite its wide use its efficacy has been demonstrated in phase three studies, they performed a randomized study comparing pneumatic compression versus no treatment in patients with post mastectomy lymphedema. Lymphedema was assessed by the sum of difference in circumference measurement between affected and normal limb, response was deducted by a 25 percent reduction in delta value.

Tiwari (2003 FEB) stated that treatment of arm lymphedema is much the same treatment for leg lymphedema, the preferred treatment is pneumatic compression. However the arm lymphedema has been shown that a treatment protocol including sequential pump therapy with manual decongestive therapy has obtained the best result.

Moosea.Y et al.; (April 2010) focused on lymphedema resulting from breast cancer surgery. Their finished review concluded that compression bandages decreases lymphedema. Pneumatic pump and lymphatic manipulation have more volume reduction of lymphedema, intermittent pneumatic compression pump provide similar benefits of soothing effect and improves functional limitation. Comparatively they are less time consuming by which more then one patient can be treated at a time.

Megens and Haris.(2004) concluded, that in management of lymphedema following treatment of breast cancer. Thirteen subjects met the criteria for experimental research, which were categorized according to scatters level of evidence, one study was graded at level five, the other at level 6, from the level of evidence and scientific rigor pneumatic compression is proved effective.

Section C

Incidence of Lymphedema among post radical mastectomy subjects.

M.J. Brennan. et al. (FEB 1998) concluded that lymphedema is a relatively frequent complication following the management of breast carcinoma, numerous therapy intervention have been offered to treat this potentially disabling and disfiguring condition consensus have not been attained among oncologist surgeon, psychiatrist concerning the appropriate treatment of lymphedema. A review of available literature suggest that a variety of traditional and commonly available technique when used appropriately in a multi diplomacy fashion, may lessen the condition and impairment associated with acquired lymphedema the role of surgery is unclear manual mechanical therapies are promising.

DINI et al. (2008) concluded, with secondary arm lymphedema is a chronic and distressing condition which affect a significant number breast cancer. A number of health professional investigated conservative therapies have been developed to help with this.

Ribeirão Preto, Rev. Latino-Am. Enfermagem. (Sept./Oct. 2009)concluded that the Breast cancer is one of the most common types among women and can lead to high morbidity and mortality rates. Surgeries performed as part of breast cancer treatment include (radical and modified) mastectomies and conservative surgeries. Independently of what type of surgery is performed, these techniques can be accompanied by axillary lymph node drainage, which may cause upper limb lymphedema. As a part of treatment, physiotherapy plays a role in postoperative physical rehabilitation, preventing and treating complications like lymphedema, decrease movement range of upper limb joints, correcting postural malalignment and sensitive alterations and, thus, promoting functional recovery and a better quality of life.

Yasir and Umer. (1998). concluded that lymphedema following radical mastectomy or axillary clearance and radiotherapy seems to be the main predisposing factor, lymphatic blockage resulting in stimuli for growth factors and cytokines with a consequent proliferation of vessels and lymphatic is one hypothesis that explains the proliferations of lymphatic vessels in the affected oedematous tissue.

Nudelman (2000) concluded that lymphedema is a common complication of cancer treatment and has been identified as the number issue by breast cancer survivors with incidence as high as 70% given the long term survivors of these women, lymphedema

is a widely prevalent condition. Infra red radiation of axillary and supraclavicular lymph nodes increases a patient's risk of lymphedema onset and progression by as much as two fold.

Section D

Studies on reliability and validity of Tonometer.

Haris and Pillar (2009) concluded, superficial lymphatic system is divided in areas called the lymphatic territories which are separated by water sheds. When the lymphatic system fails to remove its load either due to surgery or mal formation, then the fluid accumulate in that territory, anatomic connection exists across the water sheds and while they work unaided lymphatic manipulation help the movement of fluid into lymph vessels. The purpose of the study is to examine the effectiveness of a manual technique, in moving fluid and softening them, and used three tools to examine the edema patient, were given 45 minute treatment in Vodder School and cross section of patient with secondary arm lymphedema. The tools used were tonometry, multiple frequency bio electrical impedance and aerometry. All three evolution tool indicated movement of fluid to different unblocked lymphatic territories softening of tissues in some of affected limb. Tonometry proved effective and more applicable.

Deak et al. (2000) stated that Tonometer has been frequently used since its inspection as a mean to deduct fibrotic indurations in the tissues, resistance to compression, and the extent of fluid buildup. Or lymphedema. Tonometer has been frequently used, since its portable less expensive, safe, easily available and is reliable.

Golshanand Smith (2006) stated that the most common method lymphedema measurement is tonometry, most clinician does not take pre operative settings, tonometry is safe and reliable in such cases. The measurements are made with midpoint of arm and fore arm in upper limb. It relate the extent of fiber build up, and all Tonometer points were located using anatomical land mark for reproducibility.

Section E

Studies on reliability and validity of lymphedema A Functioning, Disability and Health Questionnaire.

Nele Devoogdt et al. (American Physical therapist association journal 2011) questionnaire was introduced in American Physical therapy Association journal, Lymphedema occurs frequently after axillary dissection for breast cancer and causes significant physical and psychosocial problems. To plan the treatment for lymphedema and monitor the patient's progress, arm swelling and arm function need to be assessed. The Lymph-ICF is a descriptive and evaluative tool and consists of 29 questions about impairments in function, activity limitations, and participation restrictions of patients with breast cancer and arm lymphedema. The questionnaire is divided into 5 domains: physical function, mental function, household activities, mobility activities, and life and social activities. Reliability and validity were examined on 60 patients with lymphedema and 30 patients without lymphedema.

Ridner SH. Care Cancer. (2005) author concluded that Content validity of the final version of the Lymph-ICF was very good for patients with arm lymphedema following axillary dissection. activity limitations, and participation restrictions have to be quantified with the following scale: Score 0 is no problem, Score 1 is a small

problem, Score 2 is a moderate problem, Score 3 is a severe problem, and Score 4 is a very severe problem. Because of the gradation of this scale, we chose a VAS as scoring system and preferred not to use a Likert scale, as others did.

Barranger. E, et al. J Surg Oncol. (2005) concluded that patients who experienced scoring problems because their complaints were not always present or not present for a long time, the therapist had to emphasize that they had to score their average complaints during the previous 2 weeks, as mentioned in the introduction of the questionnaire. Furthermore, a pilot version of the Lymph-ICF was constructed based on information from the literature and from complaints of patients with arm lymphedema. Afterward, the patients gave their comments on the questionnaire, which led to the construction of the final version of the Lymph-ICF.

Armer and Stewart , Lymphat Res Biol. (2005) tested the validity in 2 ways and gave good results in the patients with arm lymphedema. Each domain of the Lymph-ICF (except the life and social activities domain) had the strongest correlation and 3 of 5 domains had the weakest correlation with the expected domains of the SF-36, confirming good convergent and divergent validity, respectively. Other studies found comparable13 or slightly higher correlations12 between their questionnaire and a questionnaire already tested on reliability and validity.

III. METHODOLOGY

3.1 STUDY DESIGN:

Pre and post test experimental design.

3.2 SAMPLING DESIGN:

Consecutive sampling.

3.3 STUDY SETTING:

Lakeshore hospital, Maradu, Ernamkulam. Subjects included for the study are divided in to two groups group A and group B.

Group A Subjects received lymphatic manipulation.

Group B Subjects received intermittent pneumatic compression pump.

3.4 STUDY DURATION:

The study was conducted for a period of 12 weeks, thrice a week.

3.5 CRITERIA FOR SELECTION OF SUBJECTS:

3.5.1 Inclusion Criteria

- Women aged 40-45years treated for unilateral post radical mastectomy.
- Patient with ipsilateral lymphedema with a limb volume difference of at least 50 ml compared to lateral limb.

- Patients who have finished treatment with radio therapy, chemo therapy at least 6 months before study begins.

3.5.2. Exclusion Criteria

- Malignant lymphedema of acute appearance within one year of post intervention.
- Patient with paralysis or previous vascular disorder in the affected arm.
- Patient with major limitation of 30% or more in any of the arc of ipsilateral shoulder.
- Patient with contraindication of lymphatic manipulation, heart failure, uncontrolled hyper tension, arm impairment and radiodermatis.
- Patient who have undergone rehabilitation within three months prior to recruitment.

3.6 VARIABLES:

3.6.1. Dependent variables : Lymphedema, functional limitation.

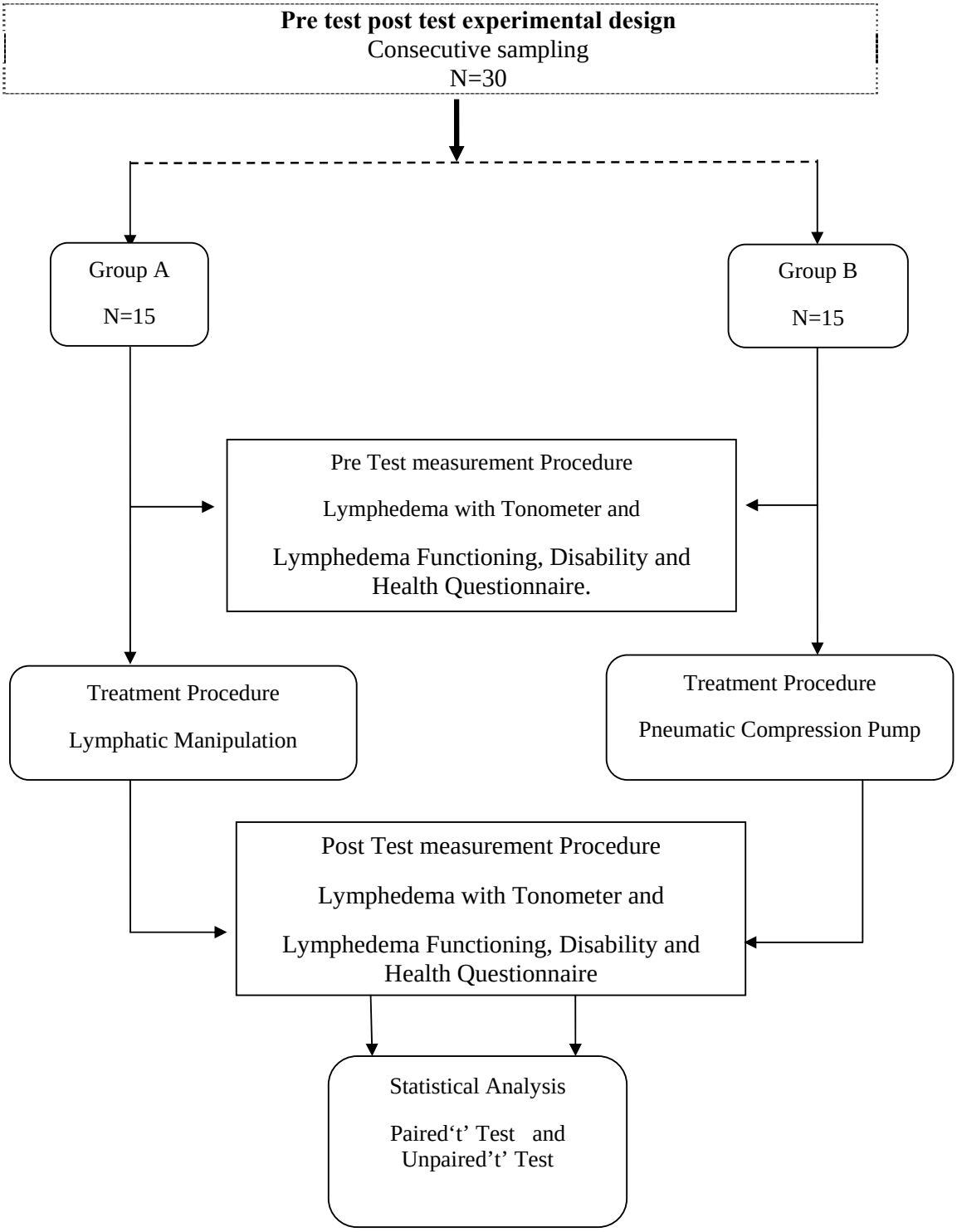
3.6.2. Independent variables : Lymphatic manipulation, intermittent pneumatic compression pump.

3.7 ASSESSMENT TOOL:

- Tonometer to measure lymphedema.
- Lymphedema Functioning, Disability and Health Questionnaire to measure functional limitation.

3.8 PROCEDURE:

Figure: 1 Flow Chart



30 medically directed unilateral lymphedema post radical mastectomy subjects from physiotherapy outpatient department aged between 40 and 55years who fulfilled inclusion and exclusion criteria were selected by consecutive sampling method and randomly assigned to two groups of 15 subjects each as Group A and Group B. Group A assigned for Lymphatic Manipulation and Group B intermittent pneumatic compression pump were measured by Tonometer and lymphedema Functioning, Disability and Health Questionnaire and recorded.

3.9 MEASUREMENT PROCEDURE:

3.9.1 Lymphedema by Tonometer

- Tonometer is a mean to detect fibrotic indurations in the tissue resistance to compression.

- Tonometer relate the extent of fiber build up, is measured by placing the weight based Tonometer over the midpoint of lymphatic territory or over water shed.

- A measurement is taken of the depth the plunger penetrates after a period of 2 second and recorded on a analogue scale.

- All Tonometer points were located using anatomical land mark for reproducibility.

Arm patient

- Fore arm
- Upper arm
- Anterior and
- posterior thorax

All Tonometer measurements was taken with patient supine and tested with muscle relaxed.

3.9.2 Functional Limitation by Lymphedema Functioning, Disability and Health Questionnaire

It is a questionnaire method consisting of five phases in 29 items Scores are dependent on the marks made by the subjects respectively in the 29 items. Before the subjects start the therapy the therapist explains the five phases and items included. If they feel the particular item is not applicable or not long term average value can be remarked or not applicable remark can be made. The five Phases are namely.

- Physical Condition
- Mental condition
- Household activity
- Mobility
- Social activity

Initially the information on impairments in function, activity Limitations, and participation restrictions was collected in 30 patients with subjective or objective lymphedema post radical mastectomy. Subjects were receiving treatment for their arm lymphedema are recruited from Lakeshore hospital.

3.10. TREATMENT PROCEDURE:

3.10.1 LYMPHATIC MANIPULATION TECHNIQUES

Lymphatic manipulation is a manual treatment based on four strokes these basic strokes known as Stationary circle, pump, rotary and scoop. Techniques are designed to manipulate lymph nodes and lymphatic vessels with the goal of increasing their activity and promote the flow of lymph.

The treatment is given in alternative working days patient positioning is supine lying with pillows to be head, the therapist stand at the side of the patient to respective arm to be treated during treatment. Fifteen Subjects treated with lymphatic manipulation are assigned to group A.

Correct pressure is to be applied, this is about 1-4 ounces. Direction of stroke is to push the lymph towards the correct nodes. Sequence is the order of the strokes to drain an area, start near the node to be drained and push the fluid back in the direction of the node. In this way we clear a path for the lymph to move, as well as create a suctioning effect that draws the lymph to the node.

Pump technique: The entire palm and the proximal (upper) phalanges are used to apply a circle-shaped pressure on the skin, operating within almost the full range of motion in the wrist. Pumps are primarily used to manipulate lymph vessels located in the extremities and can be applied with one hand or bimanually.

Rotary technique: The entire surface of the hand and fingers are used in an elliptical movement during the working phase. Like the scoop technique, rotaries are applied dynamically, meaning the working hand moves over the surface of the treated body part in a continuous fashion. If applied bimanually, the techniques are alternating.

Scoop technique: The palmer surface of the hand moves dynamically over the skin. The hand movement is facilitated by transitional movement in the wrist, combined with forearm pronation and supination.

Each technique is given five minutes with a total section of fifteen minutes after each section post test value calculated using tonometer and recorded. The pre test value are calculated and recorded at the beginning of the session and post test value at the completion of the treatment respectively after twelve weeks.

3.10.2 INTERMITTENT PNEUMATIC COMPRESSION PUMP

This is a multi-compartmental pressure system specifically designed for the treatment of primary or secondary lymphedema patients. Lymphapress utilizes a short-duration, adjustable high pressure cycle providing a sequential milking pattern to the upper or lower limb through multiple compartments. Thus, fluid moves from the distal area and progresses proximally. The unique overlapping of the twelve air

compartments within the sleeve guarantees a calibrated gradient pressure and prevents any gaps between the functioning compartments. The 30 second inflation cycles are alternated with an intermission phase to allow free flow of arterial blood. This provides a comfortable treatment and accounts for maximal patient compliance. Subject positioning is supine lying with proper pillows to the head and arms at resting position. Wrap the belt around the arm of the patient and inflate and deflate according to patients response and comfort. Each session is carried for 15 minutes and after completion of treatment remove the belt and post test values are calculated with tonometer and recorded.

IV. DATA ANALYSIS AND RESULTS

4.1.DATA ANALYSIS

The data collected from 30 subjects were evaluated statistically. Descriptive analytical study was done by using Paired‘t’ test and Unpaired ‘t’ test.

a) **Paired ‘t’ test**

$$\bar{d} = \frac{\sum d}{n}$$

$$S = \sqrt{\frac{\sum d^2 - \frac{(\sum d)^2}{n}}{n-1}}$$

$$t = \frac{\bar{d}\sqrt{n}}{s}$$

Where,

d – Difference between pre test and post test values.

—– Mean of difference between pre test and post test values.

n – Total number of subjects.

s – Standard deviation.

b) Un paired 't' test

$$s = \sqrt{\frac{\sum(x_{1-}\ \bar{x}_2)^2 + \sum(x_{2-}\ \bar{x}_2)^2}{n_1 + n_2 - 2}}$$

$$T = \frac{\bar{x}_{1-}\ \bar{x}_2}{S} \quad \sqrt{\frac{n_1 n_2}{n_1 + n_2}}$$

Where,

S = Standard deviation.

n_1 = Number of subjects in Group A.

n_2 = Number of subjects in Group B.

$\bar{x}_1$ = Mean of the difference in values between pre-test and post-test in Group-A.

$\bar{x}_2$ = Mean of the difference in values between pre-test and post-test in Group-B.

4.2. Data Analysis of lymphedema in Group A

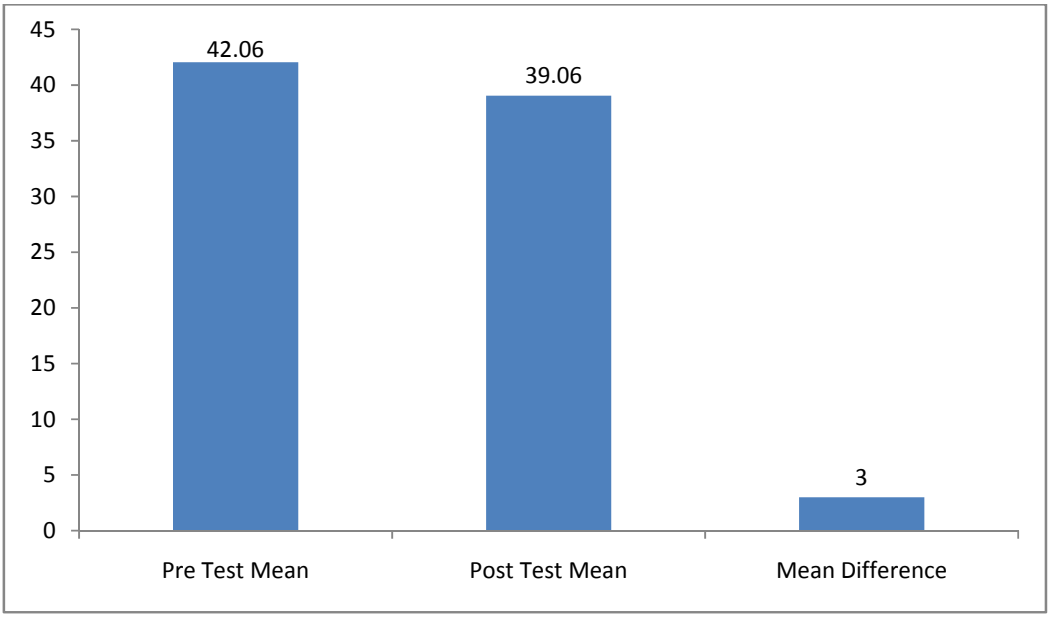
Subjects in Group A were given lymphatic manipulation for 12 weeks. Pre test, Post test scores were recorded and statistically analyzed as follows.

Table 1: Shows the mean, mean difference standard deviation paired‘t’ test value of lymphedema in group A subjects.

Measurement	Mean	Mean Difference	Standard Deviation	Paired ‘t’ value
Pre test	42.06	3	1.6	7.24
Post test	39.06			

The calculated paired’t’ value for lymphedema in Group A is 7.24. The‘t’ table value is 3.250 at 0.005 level of significance. Since the calculated‘t’ value is more than ‘t’ table value, there is significant difference in Pre and Post test scores of Group A. Thus there is significant reduction in lymphedema following lymphatic manipulation in post radical mastectomy subjects.

Figure: 2 Graphical representation of Pre test Mean, Post test Mean and Mean Difference score of lymphedema in Group A.



4.3. Data Analysis of Lymphedema in Group B

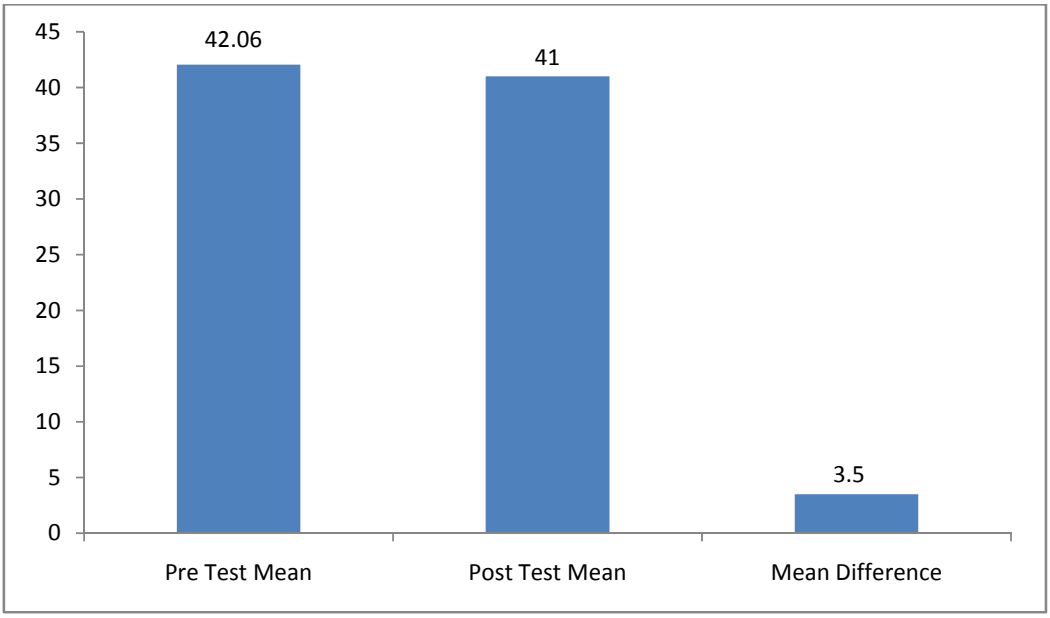
Subjects in Group B were given Intermittent Pneumatic compression Pump for 12 weeks. Pre test and Post test scores were recorded and statistically analyzed as follows.

Table: 2 Shows the mean, mean difference standard deviation paired 't' test value of lymphedema in group B subjects.

Measurement	Mean	Mean Difference	Standard Deviation	Paired 't' value
Pre test Post test	42.06 41	1.06	0.45	9.03

The calculated paired 't' value for lymphedema in Group B is 9.03. The 't' table value is 3.250 at 0.005 level of significance. Since the calculated 't' value is more than 't' table value, there is significant difference in Pre and Post test scores of Group B. Thus there is significant reduction in pain following Intermittent Pneumatic compression Pumps among lymphedema following lymphatic manipulation in post radical mastectomy subjects.

Figure: 3 Graphical representation of Pre test Mean, Post test Mean and Mean Difference score of lymphedema in Group B.



4.4. Data Analysis of Lymphedema of Group A and Group B

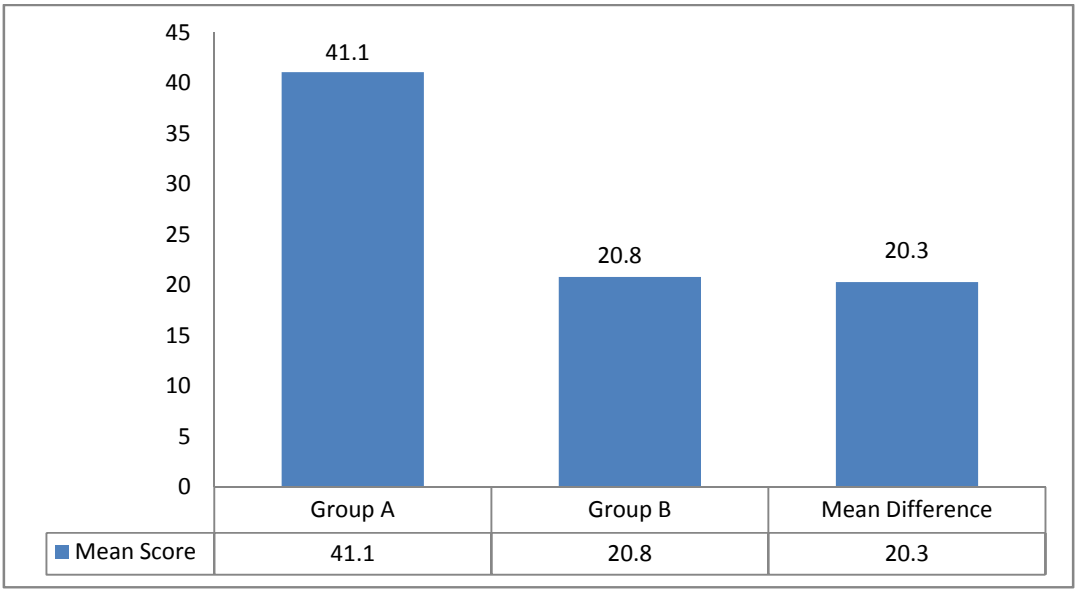
Subjects in Group A and Group B were given lymphatic manipulation and intermittent pneumatic compression pump for 12 weeks thrice a week and Pre-test, Post-test scores were recorded and statistically analyzed as follows.

Table: 3 The Mean, Mean Difference, Standard Deviation and Unpaired 't' values of Lymphedema in Group A and Group.

Serial No	Groups	Improvement		Standard Deviation	Unpaired 't' test
		Mean	Mean Difference		
1. 2.	Group A Group B	3.00 1.06	1.94	1.18	4.49

The calculated unpaired 't' value for lymphedema of Group A with Group B is 4.49. The Unpaired 't' table value is 2.878 at 0.005 level of 0 Since the calculated unpaired 't' value is more than 't' table value, there is significant difference in lymphedema score of Group A with Group B. Thus there is significant difference between Group A and Group B in reducing lymphedema among post radical mastectomy subjects.

Figure: 4 Graphical representation of Mean and Mean difference of Lymphedema values of Group A and Group B.



4.5. Data Analysis of Functional Limitations in Group A

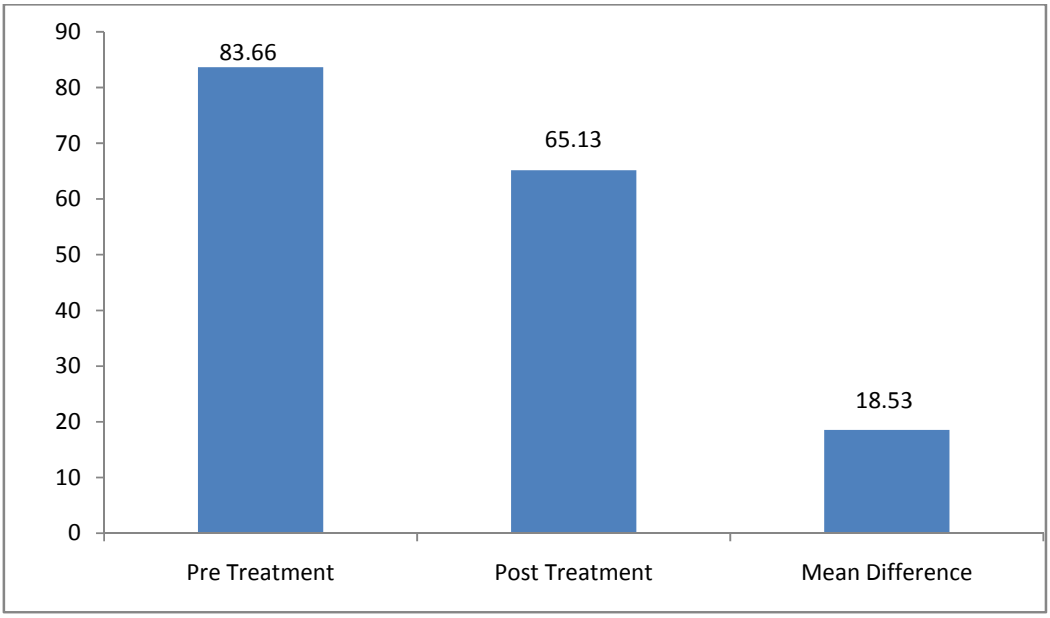
Subjects in Group A were given lymphatic manipulation for 12 week thrice in a week. Pre test, Post test scores were recorded and statistically analyzed as follows.

Table 4: The mean, mean difference, standard deviation and paired 't' value on Pre test, Post test scores of Functional Limitations in Group A.

Measurement	Mean	Mean Difference	Standard Deviation	Paired 't' value
Pre test	83.66	18.53	2.7	25.88
Post test	65.13			

The calculated Paired 't' value for Functional Limitations in Group A is 25.8. The 't' table value is 3.250 at 0.005 level of significance. Since the calculated paired 't' value is more than 't' table value, there is significant difference in Pre and Post test scores of Group A. Thus there is significant improvement in Functional Limitations following lymphatic manipulation in post radical mastectomy subjects.

Figure: 5 Graphical representation of Pre test Mean, Post test Mean and Mean Difference score of Functional Limitations in Group A.



4.6. Data Analysis of Functional Limitations in Group B

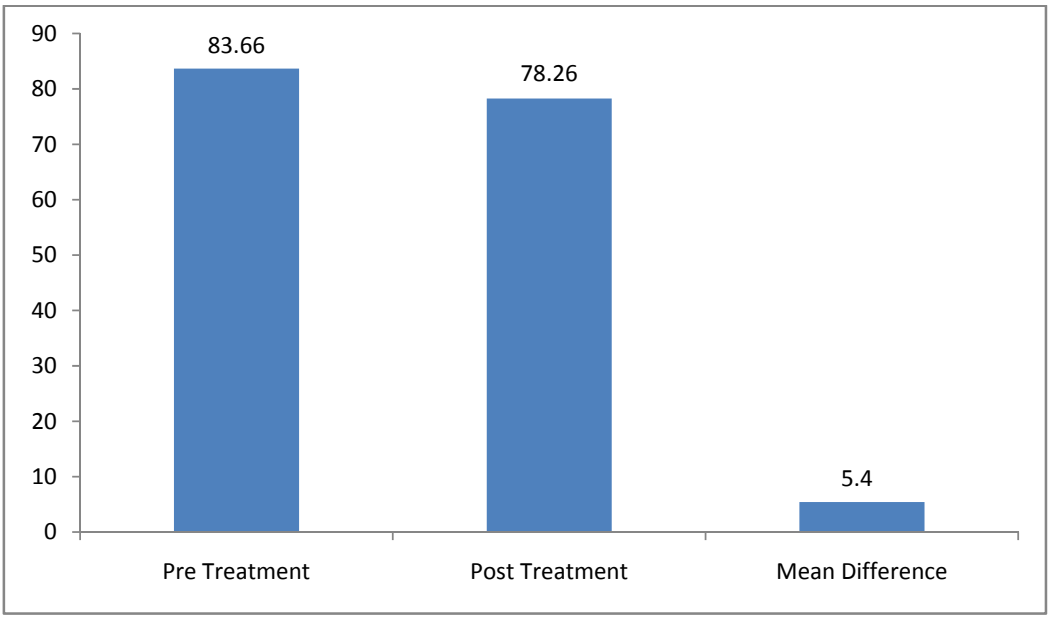
Subjects in Group B were given intermittent pneumatic compression pump for 12 weeks thrice a week. Pre test and Post test scores were recorded and statistically analyzed as follows.

Table: 5 The Mean, Mean Difference, Standard deviation and Paired 't' value on Pre test, Post test scores of Functional Limitations in Group B.

Measurement	Mean	Mean Difference	Standard Deviation	Paired 't' value
Pretest	83.66	5.4	1.24	16.84
Post test	78.26			

The calculated paired 't' value for Functional Limitations in Group B is 7.87. The paired 't' table value is 3.250 at 0.005 level of significance. Since the calculated paired 't' value is more than 't' table value, there is significant difference in Pre and Post test scores of Group B. Thus there is significant improvement in Functional Limitations following intermittent pneumatic compression pump post radical mastectomy subjects.

Figure: 6 Graphical representation of Pre test Mean, Post test Mean and Mean Difference score of Functional Limitations in Group B.



4.7. Data Analysis of Functional Limitations of Group A and Group B

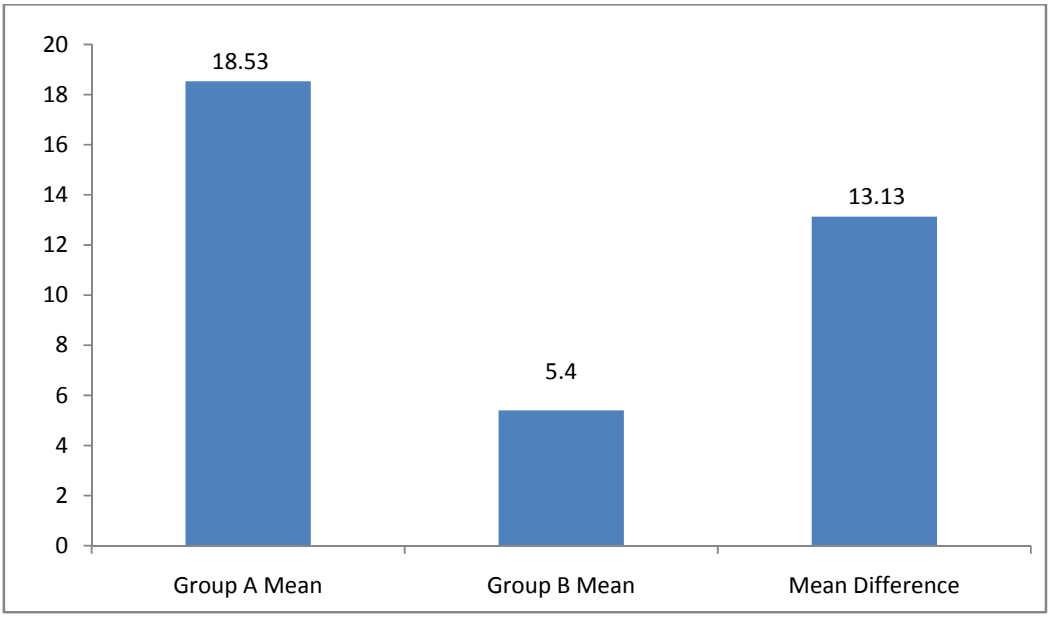
Subjects in Group A and Group B were given lymphatic manipulation and intermittent pneumatic compression pump for 12 weeks thrice a week and Pre-test, Post-test scores were recorded and statistically analyzed as follows.

Table: 6 The Mean, Mean Difference, Standard Deviation and Unpaired 't' values of Functional Limitations in Group A and Group B.

Serial No	Groups	Improvement		Standard Deviation	Unpaired 't' test
		Mean	Mean Difference		
1.	Group A	18.53	13.13	2.15	16.74
2.	Group B	5.40			

The calculated unpaired 't' value for Functional Limitations of Group A with Group B is 6.331. The Unpaired 't' table value is 2.878 at 0.005 level of significance. Since the calculated Unpaired 't' value is more than 't' table value, there is significant difference in Functional Limitations score of Group A with Group B. Thus there is significant difference between Group A and Group B in improving Functional Limitations among post radical mastectomy subjects.

Figure: 7 Graphical representation of Mean and Mean difference of Functional Limitations values of Group A and Group B.



4.8. Results

The number of subjects for the study was 30 (N=30).The subjects were divided into two groups , Group ‘A’ and Group ‘B’, each group consisting of 15 subjects. Total treatment program was for a period of 12 weeks at approximately 15 minutes per session thrice a week. Before the treatment started Group A and Group B were involved for pre-test assessment by tonometry for lymphedema and lymphedema Functioning, Disability and Health Questionnaire for functional limitation. Post-test assessments were repeated after the treatment for both the Groups. Group A was treated with lymphatic manipulation and Group B was treated with intermittent pneumatic compression pump.

The calculated paired‘t’ value for lymphedema in Group A is 7.24 and Group B is 9.03. The‘t’ table value is 3.250 at 0.005 level of significance. Since the calculated‘t’ value is more than ‘t’ table value, there is significant difference in Pre and Post test scores of lymphedema in Group A and Group B. Thus there is significant reduction in lymphedema following lymphatic manipulation and pneumatic compression pump among post radical mastectomy subjects.

The calculated paired ‘t’ value for Functional limitation in Group A is 25.88 and Group B is 16.84. The ‘t’ table value is 3.250 at 0.005 level of significance. Since the calculated ‘t’ value is more than ‘t’ table value, there is significant difference in Pre and Post test scores of Functional limitation in Group A and Group B. Thus there is significant improvement in Functional limitation following lymphatic manipulation and intermittent pneumatic compression pump among post radical mastectomy subjects.

The calculated unpaired ‘t’ value of lymphedema of Group A and Group B for lymphedema is 4.49 and 16.74 for functional limitation. The ‘t’ table value is 2.878 at 0.005 level of significance. Since the calculated Unpaired ‘t’ value is more than ‘t’ table value, there is significant difference in lymphedema and functional limitation among Group A and Group B. Thus there is significant difference between Group A and Group B in reducing lymphedema and functional limitation for post radical mastectomy subjects. So we accept Alternate hypothesis H_{A1} and H_{A2} and reject Null hypothesis H_{01} and $H_{02.}$

V. CONCLUSION

5.1 Conclusion

A Pre-test, Post-test Experimental study was conducted to compare the effect of lymphatic manipulation and pneumatic compression pump in improving lymphedema for post radical mastectomy.

30 subjects with lymphedema in post radical mastectomy were included in this study by Consecutive sampling and randomly assigned to two groups as Group A and Group B consisting of 15 subjects each. Group A was treated with lymphatic manipulation and Group B was treated with intermittent pneumatic compression pump. Lymphedema were assessed before and after the intervention by tonometry and functioning limitation by questionnaire.

When comparing the lymphedema and functional limitation, mean values of Group A and Group B. Group A subjects who received lymphatic manipulation showed more difference than Group B who received intermittent pneumatic compression pump.

Hence it is concluded that lymphatic manipulation is more effective than intermittent pneumatic compression pump in reducing lymphedema and functional limitation in post radical mastectomy subjects.

5.2 Limitations

The study was conducted with a sample size of 30, the age group of the sample being 40 to 55 years with treatment duration of 12 weeks thrice a week.

5.3 Recommendations

Future research can be conducted with a bigger sample size, wider age group, different variables, more consistent outcome measures and different treatment durations.

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VII ANNEXURE

A.I. Annexure:

ASSESSMENT CHART

Physical Therapy Assessment Chart

Name :

Age :

Gender :

Occupation :

Chief complaints :

Medical history

- Past :
- Present:

Family history :

Social history :

Associated problems :

On observation

- Body Built :
- Posture :

- Attitude of limbs :
- Muscle wasting :
- Edema :
- Involuntary movement :
- Gait :
- Deformity :

On palpation

- Tenderness :
- Swelling :
- Muscle tightness :
- Warmth :
- Other if any :

Pain assessment

- Side :
- Site :
- Duration :
- Nature :

- Aggravating factor :
- Relieving factor :
- Other if any :

On examination

- Vital signs :
- Motor Assessment :
    - Range Of Motion :
    - End Feels :
    - Manual Muscle Testing:
    - Joint Positions :
- Sensory Assessment
    - Superficial Sensations:
    - Deep Sensations :
    - Combined :
- Reflexes
    - Superficial :
    - Deep :
    - Clonuses :

- Dermatomes and Myotomes :
- Limb Length Discrepancies :
- Special Tests :
- Functional Assessments :
- Gait Assessments :

Investigations :

Clinical Impression :

Differential Diagnosis :

Final Diagnosis :

Goals

- Short Term Goals :
- Long Term Goals :

Treatment Plan

- Intermittent pneumatic compression pump :
- Lymphatic Manipulations :

Home Assessments :

A.II. Annexure:

Lymphedema Functioning, Disability and Health Questionnaire

In Sections A, B and C questions are asked in the following format. Please mark your answers by putting an "**X**" in one of the boxes.

Serial No.	Question	None	Mild	Moderate	Severe	Extreme	Not Applicable / Remarks
	Scores	0	1	2	3	4	
Physical							
1	Heavy						
2	Stiff						
3	Swollen						
4	Lost Strength						
5	Tingle						
6	Hurt						
7	Tensed Skin						
Mental							
8	Feel Sad						
9	Feel Discouraged						
10	Lack of Self Confidence						
11	Feel Stressed						
Household Activity							
12	Clean						
13	Cook						
14	Iron						
15	Garden						
Mobility							
16	Lift Heavy objects						
17	Sleep on affected side						
18	Work on computer						
19	bathe						
20	Drive						
21	Walk more than 2 Km						
22	Cycle						
23	Task with elevated arms						
Social Life							
24	Go for picnic						
25	Perform Hobbies						
26	Practice Sports						
27	Wear Cloths of choice						
28	Do a job						
29	Do Social activities						

A.III. Annexure:

Raw Scores

A.3.1 Calculation for Pre and post-test values of lymphedema using tonometry among Group A.

Serial No.	Pre treatment	post treatment	x_1	$x_{1-}\ \bar{x}_1$	$(x_{1-}\ \bar{x}_1)^2$	x_1^2
1	43	38	5	2	4.00	25
2	42	40	2	-1	1.00	4
3	45	41	4	1	1.00	16
4	46	41	5	2	4.00	25
5	40	38	2	-1	1.00	4
6	41	39	2	-1	1.00	4
7	45	42	3	0	0.00	9
8	44	41	3	0	0.00	9
9	38	36	2	-1	1.00	4
10	39	37	2	-1	1.00	4
11	44	38	6	3	9.00	36
12	42	37	5	2	4.00	25
13	43	41	2	-1	1.00	4
14	41	40	1	-2	4.00	1
15	38	37	1	-2	4.00	1
∑	**631**	**586**	**45**	**0**	**36.00**	171
		$\bar{x}_1$=	**3**			

A.3.2 Calculation for Pre and post-test values of lymphedema using tonometry among Group B.

Serial No.	Pre treatment	post treatment	x_2	$x_{2-}\ \bar{x}_2$	$(x_{2-}\ \bar{x}_2)^2$	x_2^2
1	43	42	1	-0.06	0.00	1
2	42	41	1	-0.06	0.00	1
3	45	44	1	-0.06	0.00	1
4	46	45	1	-0.06	0.00	1
5	40	39	1	-0.06	0.00	1
6	41	39	2	0.94	0.88	4
7	45	44	1	-0.06	0.00	1
8	44	43	1	-0.06	0.00	1
9	38	38	0	-1.06	1.12	0
10	39	38	1	-0.06	0.00	1
11	44	43	1	-0.06	0.00	1
12	42	41	1	-0.06	0.00	1
13	43	42	1	-0.06	0.00	1
14	41	39	2	0.94	0.88	4
15	38	37	1	-0.06	0.00	1
∑	**631**	**615**	**16**	**0.1**	**2.934**	**20**
		$\bar{x}_2$=	**1.066667**			

A.3.3. Calculation for Pre and post-test values of functional limitation in Group A using Lymphedema Functioning, Disability and Health Questionnaire.

Serial No.	Pre treatment	post treatment	x_1	$x_1 - \bar{x}_1$	$(x_1 - \bar{x}_1)^2$	x_1^2
1	76	57	19	0.47	0.22	361
2	77	63	14	-4.53	20.55	196
3	88	71	17	-1.53	2.35	289
4	80	62	18	-0.53	0.28	324
5	95	78	17	-1.53	2.35	289
6	78	60	18	-0.53	0.28	324
7	98	83	15	-3.53	12.48	225
8	73	52	21	2.47	6.08	441
9	92	70	22	3.47	12.02	484
10	72	56	16	-2.53	6.42	256
11	82	61	21	2.47	6.08	441
12	84	67	17	-1.53	2.35	289
13	86	65	21	2.47	6.08	441
14	80	56	24	5.47	29.88	576
15	94	76	18	-0.53	0.28	324
∑	**1255**	**977**	**278**	**0.00**	**107.73**	5260
		$\bar{x}_1$=	18.53333			

A.3.4 Calculation for Pre and post-test values of functional limitation in Group B using lymphedema Functioning, Disability and Health Questionnaire.

Serial No.	Pre treatment	post treatment	x_2	$x_2 - \bar{x}_2$	$(x_2 - \bar{x}_2)^2$	x_2^2
1	76	71	5	-0.40	0.16	25
2	77	72	5	-0.40	0.16	25
3	88	80	8	2.60	6.76	64
4	80	74	6	0.60	0.36	36
5	95	89	6	0.60	0.36	36
6	78	74	4	-1.40	1.96	16
7	98	91	7	1.60	2.56	49
8	73	69	4	-1.40	1.96	16
9	92	86	6	0.60	0.36	36
10	72	67	5	-0.40	0.16	25
11	82	75	7	1.60	2.56	49
12	84	80	4	-1.40	1.96	16
13	86	81	5	-0.40	0.16	25
14	80	76	4	-1.40	1.96	16
15	94	89	5	-0.40	0.16	25
∑	**1255**	**1174**	**81**	81.00	**21.6**	**459**
		$\bar{x}_2$=	5.4			

A.IV.Annexure:

Gallery

Tonometer

Intermittent pneumatic pump

Assessment with Tonometer

Intermittent pneumatic compression pump

Lymphatic manipulation rotary technique

Lymphatic manipulation pump technique

Lymphatic manipulation scoop technique

A.V. Annexure:

PATIENT CONSENT FORM

I ……aged……yrs, voluntarily consent to participate in the research named **"A COMPARATIVE STUDY OF LYMPHATIC MANIPULATION VERSUS INTERMITTENT PNEUMATIC COMPRESSION PUMP TO REDUCE LYMPHEDEMA AND ITS RELATED FUNCTIONAL LIMITATION IN POST RADICAL MASTECTOMY"**

The researcher has explained me the treatment approach in brief, risk of participation and has answered all the questions pertaining to the study to my satisfaction.

Signature of Subject **Signature of Researcher**

Signature of Witness